

REMARKS

The above-captioned patent application has been carefully reviewed in light of the final Office Action to which this Amendment is responsive. Claim 9 has been amended in a further effort to clarify the present invention while Claims 1, 6 and 10-17 have been canceled.

Claims 1, 6, 9 and 11-17 were pending in the above-captioned application. Because Claims 1, 6 and 12-17 have been canceled, it is believed all outstanding rejections of these claims have been rendered moot. Therefore, the remainder of these remarks are directed to the rejection of Claim 9 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully requests reconsideration based on the amended version of Claim 9, as well as the following discussion.

Applicant gratefully acknowledges the telephonic interview granted by Examiner Brian R. Gordon with Applicant's representative, Peter J. Bilinski, on November 25, 2008. The subject matter that was discussed during the interview is included in this correspondence.

According to the Examiner, the claims contain subject matter which was not described in the specification in such a way that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner has argued that Applicant has merely referred to "sporadic portions of the present specification" in an effort to show the claimed invention. The Examiner has also indicated that "tables" and/or other materials must be produced in order to evidence that a "method-type" invention is present. Applicant acknowledges that Claims 9 is not an originally filed claim of the application. However, Applicant disagrees that this overly prescriptive level of production is required as opined by the Examiner and further submits that more than adequate enablement and description as required by the Statute is herein provided by the original specification and drawings for the pending claim.

The claimed invention relates to a method of optically reading a residual (dead) volume in a metering tip. The metering tip includes a tip nozzle as well as an interior that includes stepped area disposed above a cylindrical section defining a read window. The stepped area includes a sharp diametrical edge and enables an upper meniscus of this dead volume to be latched and subsequently flattened so as to permit a more accurate optical measurement with a minimized residual fluid volume. A problem confronted in the art is having to have an excessive residual volume in the tip in order to obtain a suitable optical reading in the read window. One

reason for this is the result of fluid properties including that of a cupped upper meniscus, which interferes with an accurate optical reading.

In general, the above-captioned application describes an improved method for reading the dead volume. According to this method, samples are first dispensed from an initially aspirated fluid volume contained in the tip through the tip nozzle. In order to enable the stepped area to be used properly, it is first required that the residual fluid left in the tip be drawn upwardly into the tip nozzle. This is done by aspirating an air bubble into the tip prior to sealing the lower tip opening. The air bubble achieves two functions, as described at paragraph [0028] of the application. The air bubble insulates the fluid from heat created as a result of the sealing operation. Second, the air bubble causes the fluid to be drawn upwardly into the tip such that the upper meniscus of the fluid is latched and “flattened” by the stepped area above the read window, as is shown by contrasting Figs. 11 and 12. Due to the flattening of the upper meniscus, a smaller volume of residual fluid is required to successfully perform an optical read.

By way of background and prior to discussing Claim 9 in detail, support is found for each of the features noted above with reference to the above-captioned application, as now detailed.

First, the Examiner is directed to paragraph [0012]:

“According to a preferred embodiment, at least one stepped area is provided in relation to a read area of the metering tip to permit examination of a minimized fluid dead volume remaining in the tip.”

Referring further to paragraph [0014]:

“another advantage is that providing a stepped area relative to the read area of the tip permits optical tests, such as spectrophotometric readings, to be reliably performed using a minimized dead volume in the tip.”

Referring to the Brief Description of the Drawings, at paragraph [0021]:

“Fig. 12 illustrates the creation of a dead fluid volume for optical read purposes in a metering tip made in accordance with the present invention.”

In the Detailed Description of the captioned application, referring to paragraph [0026], the term “dead volume” is defined:

“... after all of the samples have been dispensed from the metering tip 60, it is often desired to take a spectrophotometric read of the fluid remaining in the tip (this fluid is subsequently referred to throughout as “dead volume”).

Referring to paragraph [0027], the actual read process is described with reference to Fig. 12:

“Referring to Fig. 12, a spectrophotometric read is taken through a read window 96 located in a cylindrical portion 74 of the tip immediately below another defined stepped area 78 and above the external cone.”

The need for sealing the tip is described in paragraph [0027]:

“Removing the tip 60 with the nozzle 64 open to air would likely cause loss of the fluid or dispersal of the fluid within the tip. Were this to occur, fluid would not be properly positioned for the spectrophotometric read. One effective solution to this problem is to seal the tip 60 by contacting tip to a heated anvil (not shown), melting the end of the tip nozzle. The sealed tip effectively becomes a “cuvette” which can be stored in a storage device (not shown) for a later spectrophotometric read.”

Continuing within paragraph [0028]:

“... prior to sealing, the dead volume of fluid is first drawn up into the nozzle of the metering tip 60....it is highly desirable to minimize the dead volume, especially when the fluid is a pediatric sample.”

The drawing operation is discussed at paragraph [0029]:

“... the aspirated air bubble elevates the upper meniscus 98 of the dead volume 94 so that there are no optical effects due to the upper meniscus during the spectrophotometric read.”

The stepped area above the read window and its effect on the drawn-in residual fluid is detailed in paragraph [0030]:

Still referring to Fig. 12, and to further reduce the optical effect of the upper meniscus, another internal stepped area 92 is added within the tip 60 just above the spectrophotometric read area window 96. Without this stepped area 92 and referring to the prior art nozzle depicted in Fig. 11, the upper meniscus 88 would assume an approximately spherical curvature depending on surface tension. At the low end of tolerance of dead volume, the curvature could cause optical reflection, thereby effecting the spectrophotometric read accuracy. Also, due to the shock of tip ejection and subsequent transport in the storage device (not shown), the upper meniscus 88 could tilt so that the low side of the meniscus could

extend well into the optical path of the spectrophotometer. The effect of the stepped area 92 is to effectively "latch" and thereby flatten the meniscus 88.

With this background, it has been noted that Claim 9 has now been amended to clarify the inventive method and is herein reproduced. The newly amended portions are highlighted by underline and the deleted portions are shown as stricken, as follows:

9. A method for performing an optical read of dead volume of fluid in a metering tip, said tip containing a volume of aspirated fluid, a portion of said fluid being dispensed as samples, said tip comprising at least one stepped area within an interior of said tip, said at least one stepped area including a sharp diametrical edge, said method including the steps of:

i) attaching a metering tip to a metering apparatus;

ii) aspirating a volume of fluid into said metering tip using said metering apparatus, said tip comprising at least one stepped area within the interior of the metering tip, each said at least one stepped area including a sharp diametrical edge at the junction of the surface of an interior region and surface of the stepped area, said surfaces being substantially orthogonal;

iii) dispensing a portion, but not the entirety, of samples from the volume of aspirated fluid from said metering tip through said a lower tip opening wherein said dispensed portion of fluid is moved over the sharp diametrical edge of said at least one stepped area so as to latch a lower meniscus of the fluid passing said at least one stepped area and thereby reducing oscillation of the fluid in the metering tip;

iv) ii) aspirating an air bubble into said tip, thereby drawing the remaining fluid retained in said metering tip upwardly and into a an axial cylindrical section of said metering tip, said axial cylindrical portion being defined with a substantially constant planar internal diameter defining a read window wherein one of said at least one stepped areas area is located above said read window, wherein said stepped area above said read window flattens the upper meniscus of said retained volume of fluid; and

- iii) sealing the lower tip opening of said metering tip; and
- iv) optically reading the retained volume through said defined read window.

Support for each element recited by the foregoing amended Claim 9 is provided as follows, since this claim is not an originally drafted claim of the application.

“A method for performing an optical read of dead volume in a metering tip” --- Support is provided at paragraph [0012], and more specifically the last sentence of this paragraph. See also paragraph [0014]. Support for the method of providing an optical read is also provided at Fig. 12, which clearly illustrates drawn in residual “dead” volume within the tip and the effect of the stepped area on the upper meniscus of the drawn-in fluid.

“said tip containing a volume of aspirated fluid” - Support is provided at paragraph [0024] as well as Figs. 4-10 that illustrate fluid within the tip for dispense of a sample in a time-phased sequence.

“a portion of said fluid being dispensed as samples” is provided, for example, in the time-phased drawings Figs. 4-10 and also at paragraph [0026], second sentence, in which it is specifically indicated that samples are dispensed from the tip and a residual volume (dead volume) remains after all samples have been dispensed.

“said tip comprising at least one stepped area within an interior of said tip, said at least one stepped area including a sharp diametrical edge.” - Support is found generally at paragraph [0024], first and second sentences and Fig. 3. See also paragraph [0027], first sentence and Fig. 12.

“dispensing samples from the volume of aspirated fluid from said metering tip through a lower tip opening” - Support is provided at paragraph [0024], as well as Figs. 4-10 that illustrate time-phased sequences of fluid sample being aspirated from the tip. Reference is also made to

paragraph [0026], second sentence, which refers specifically to the dispensing of samples from the confines of the metering tip.

“aspirating an air bubble into said tip” ---- Support for this limitation is provided at paragraph [0028], see entire paragraph as well as paragraph [0029], first sentence. The Examiner is also requested to refer to Figs. 11 and 12, in which an air bubble 80 is depicted according to Fig. 11 and shown (but unlabeled) in Fig. 12.

“, thereby drawing the remaining fluid in said metering tip upwardly and into a cylindrical section of said metering tip” - Support is provided at paragraph [0028], first sentence and also with reference to the dead volume 94 shown in Fig. 12. The cylindrical section itself is also noted at paragraph [0027], first sentence.

“said cylindrical portion being defined with a substantially constant planar internal diameter defining a read window” - Support is provided at paragraph [0027] referring to cylindrical portion 74 and Figs. 12 as compared also to Fig. 11.

“wherein at least one stepped area is located above said read window” - Support is provided at paragraph [0030], lines 1-2, “another internal stepped area is added within the tip 60 just above the spectrophotometric read window 96”.

“wherein said stepped area flattens the upper meniscus of said retained volume of fluid” - Support is provided at paragraph [0030], lines 7-8, “The effect of the stepped area 92 is to effectively “latch” and thereby flatten the meniscus 88.”

“sealing the lower tip opening of said metering tip” – Support for this limitation is found at paragraph [0027] “One effective solution to this problem is to seal the tip 60 by contacting the tip to a heated anvil (not shown), melting the end of the tip nozzle.”

"optically reading the retained volume through said retained read window" - Support is provided at paragraph [0027], first sentence. Reference is also made to Fig. 12.

Pursuant to MPEP §2163.04, a description is presumed to be adequate unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. As to later added claimed subject matter, the description should reasonably convey to the artisan that the inventor had possession at the time of the later claimed subject matter. This possession can be made in a variety of ways and need not be described literally (using the same terms or in haec verba) to satisfy this element.

To that end, Applicant believes by way of the foregoing that sufficient description is provided and therefore it is believed the subject matter of Claim 9 is clearly supported by the original patent application, including the drawings. Reconsideration is respectfully requested, as well as withdrawal of the instant Section 112 rejection.

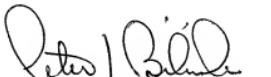
In summary and in view of the above amendment, Applicant believes the above-captioned application is now in a condition for allowance and an expedited Notice of Allowability is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicant's representative at the telephone number listed below.

It is believed no fees are required for the filing of this response other than the filing fee for the Request for Continued Examination (RCE), which accompanies this correspondence. However, in the event that any additional fees are required, the Director is hereby authorized to charge Deposit Account No. 50-3010 for any additional fees and to charge any overpayments thereto.

Respectfully submitted,
HISCOCK & BARCLAY, LLP

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Peter J. Bilinski
Reg. No. 35,067
Hiscock & Barclay, LLP
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 425-2856
Fax: (315) 703-7397